REMARKS

The Office Action of June 16, 2006 presents the examination of claims 6-12.

Substance of Interview

A telephone interview was conducted with the Examiner on October 27, 2006. The remarks herein reflect the substance of that interview.

Rejection over Dunn

Claims 6-10 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dunn '789. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that the Examiner fails to establish *prima facie* obviousness of the presently claimed subject matter. In particular, the cited reference fails to disclose or suggest all of the features recited in the rejected claims.

As explained in the interview of October 27, 2006, a principal difference between the Dunn '789 reference and the present invention is that the present invention, as described by claim 6, comprises

> A ***cured*** sustained-release formulation for implantation, which comprises one of particle combinations, which is selected from a group consisting of (a), (b) and (c), ...
>
> (a) a particle combination which comprises ... particles comprising a carbonate, and particles comprising a substance which reacts with the carbonate in an aqueous solution to generate carbon dioxide;
>
> (b) a particle combination which comprises particles comprising ... a carbonate, and particles comprising a substance which reacts with the carbonate in an aqueous solution to generate carbon dioxide; and
>
> (c) a particle combination which comprises particles comprising a carbonate, and particles comprising ... a substance which reacts with the carbonate in an aqueous solution to generate carbon dioxide ... .

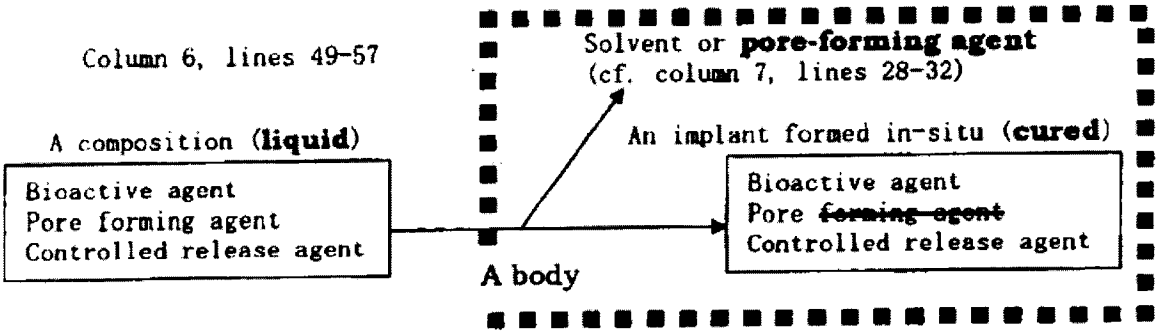
So, being a ***cured*** composition, the composition of the invention is a ***solid*** composition, not a liquid or a gel, in which form it includes particles comprising a carbonate and particles comprising a substance that reacts with the carbonate to form carbon dioxide. The solid nature of the present invention is also stated in claim 7, which recites that the composition has a particular shape. A liquid or gel composition cannot maintain a shape.

As explained in previous responses, the presently claimed composition is administered to the body in a solid form, after which body fluids permeate the composition, leading to dissolution and mixing of the carbonate and carbonate-reactive particles, resulting in formation of carbon dioxide gas that breaks apart the solid composition to forms cracks and channels in the solid composition.

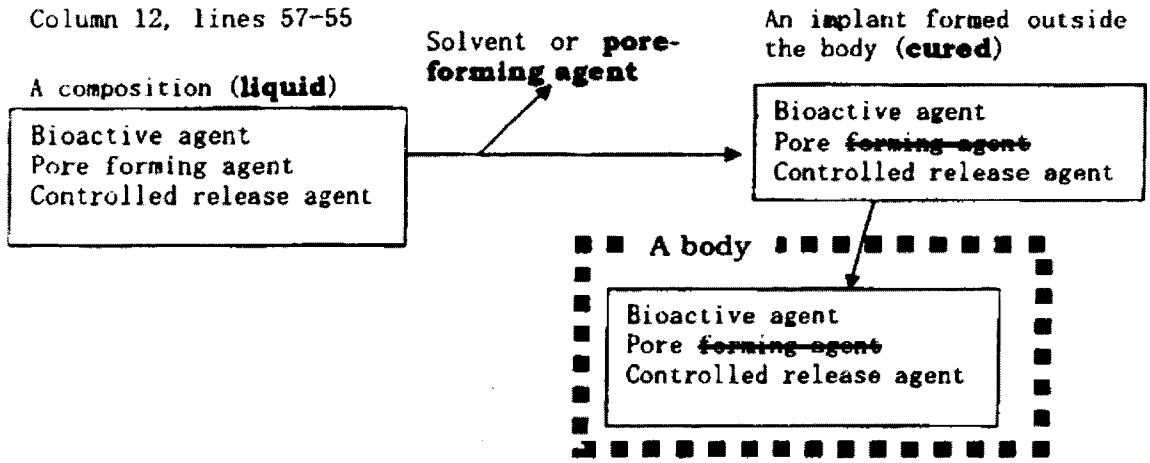
On the other hand, the compositions disclosed by Dunn are liquid in form. The Examiner has taken a position that Dunn '789 includes a solid composition, because the reference discloses that the composition can be polymerized or dried outside the body, on a substrate, and then the so solidified composition administered to the body. (The Examiner refers to col. 6, lines 49-57 and to col. 12, lines 53-55.)

However, as explained in the interview, as the composition of Dunn is solidified, the pore forming agent or solvent leaves the composition, and in so doing leaves behind the pores and channels in the solidified composition. Thus, once the composition of Dunn '789 is solidified, it no longer includes the solvent or pore forming agent (*i.e.* carbonate and substance reacting with carbonate). At column 7, lines 28-32, Dunn '789 describes that the pore forming agent disperses, dissipates, or dissolves during curing.

The two circumstances described by Dunn '789 are illustrated below.



Dunn's composition administered as a liquid



Dunn's composition "administered" as a solid

Since Dunn '789 does not in any way disclose or suggest that a ***solid*** composition should include a pore-forming agent, Dunn '789 does not disclose or suggest the present invention.

As also explained previously, the present invention utilizes a ***polymeric matrix*** (... "carrier comprising a hydrophobic polymer..."). In contrast, Dunn '789 is expressly a non-polymeric composition. See, col. 3, line 31 and line 44.

Thus, for either of these reasons independently, or both together, it is plain that Dunn '789 in no way discloses or suggests the invention as presently claimed. Accordingly, the rejection of claims 6-10 and 12 under 35 U.S.C. § 103(a) over Dunn '789 should be withdrawn.

Rejection over Dunn in view of Fujioka

Claims 6-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dunn '789 in view of Fujioka '253. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit again that the Examiner has failed to establish *prima facie* obviousness of the claimed invention. In particular, there is no motivation to combine the references in the manner suggested by the Examiner. Combining the references in the manner suggested by the Examiner results in inoperability of the invention of Dunn.

The Examiner states that it would have been obvious for one of ordinary skill in the art to modify the sustained release solid matrix of Dunn using a silicone polymer in view of the teaching of Fujioka. However, as Applicants have previously argued and explain further below, there is no motivation to modify the solid formulation of Dunn with the silicone polymer disclosed in Fujioka.

Dunn repeatedly stresses the advantage of applying the composition in a liquid form, either for the purpose of filling a void in a body part, or for coating a surface of a substrate prior to implantation of the coated substrate. On the other hand, the silicone polymer composition of Fujioka would result in a composition that does not have the flow properties emphasized by Dunn as essential to his invention, and thus one of ordinary skill in the art would avoid use of a silicone polymer according to Fujioka. Furthermore, Dunn expressly describes his composition as non-polymeric, in direct distinction to what is disclosed by Fujioka.

Thus, it is plain that the combination of Dunn with Fujioka results in a direct contradiction of the express teachings of Dunn. If the silicone polymer of Fujioka is substituted for the

liquid, non-polymeric carrier of Dunn, then Dunn's invention is rendered inoperable for its intended purpose of flowing into a void or to coat a surface. Accordingly, the combination of Dunn with Fujioka is inappropriate for asserting *prima facie* obviousness of the present invention, and the instant rejection must be withdrawn.

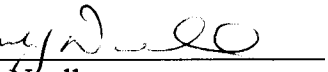
Applicants submit that the present claims 6-12 are allowable over the prior art of record. The favorable action of allowance of the claims is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: November 9, 2006

Respectfully submitted,

By 

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